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| APPLICATION NO.              | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-----------------|----------------------|---------------------|------------------|
| 10/722,184                   | 11/25/2003      | Jeffrey O. Phillips  | 03207556            | 7922             |
| 26565                        | 7590 01/09/2006 |                      | EXAM                | INER             |
| MAYER, BROWN, ROWE & MAW LLP |                 |                      | CHANG, CELIA C      |                  |
| P.O. BOX 282                 | .8              |                      |                     |                  |
| CHICAGO, IL 60690-2828       |                 |                      | ART UNIT            | PAPER NUMBER     |
|                              |                 |                      | 1625                |                  |

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | A matter Atom Atom                                                                                                                                                  | Anniloonto                                                                   |  |  |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|--|--|--|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Application No.                                                                                                                                                     | Applicant(s)                                                                 |  |  |  |  |
| Office Action Occurrence                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 10/722,184                                                                                                                                                          | PHILLIPS, JEFFREY O.                                                         |  |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Examiner                                                                                                                                                            | Art Unit                                                                     |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Celia Chang                                                                                                                                                         | 1625                                                                         |  |  |  |  |
| <ul> <li>The MAILING DATE of this communication app</li> <li>Period for Reply</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                  | ears on the cover sheet with the c                                                                                                                                  | orrespondence address –                                                      |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period versilled to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | .  nely filed  the mailing date of this communication.  D (35 U.S.C. § 133). |  |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 Ju                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ılv 2005                                                                                                                                                            | -                                                                            |  |  |  |  |
| ·— ·                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | action is non-final.                                                                                                                                                |                                                                              |  |  |  |  |
| 3) Since this application is in condition for allowar                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                     | secution as to the merits is                                                 |  |  |  |  |
| closed in accordance with the practice under E                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                     |                                                                              |  |  |  |  |
| closed in accordance with the practice under E                                                                                                                                                                                                                                                                                                                                                                                                                                                            | n purto quayro, 1000 C.B. 11, 40                                                                                                                                    | 0.0.210.                                                                     |  |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 4)⊠ Claim(s) 151-218 is/are pending in the applicat                                                                                                                                                                                                                                                                                                                                                                                                                                                       | tion.                                                                                                                                                               |                                                                              |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 5) Claim(s) is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 6) Claim(s) is/are rejected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 7) Claim(s) is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 8) Claim(s) 151-218 are subject to restriction and                                                                                                                                                                                                                                                                                                                                                                                                                                                        | or election requirement.                                                                                                                                            |                                                                              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | ·                                                                                                                                                                   |                                                                              |  |  |  |  |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 9)☐ The specification is objected to by the Examine                                                                                                                                                                                                                                                                                                                                                                                                                                                       | r.                                                                                                                                                                  | •                                                                            |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acc                                                                                                                                                                                                                                                                                                                                                                                                                                                                | epted or b) $\square$ objected to by the $\mathfrak l$                                                                                                              | Examiner.                                                                    |  |  |  |  |
| Applicant may not request that any objection to the                                                                                                                                                                                                                                                                                                                                                                                                                                                       | drawing(s) be held in abeyance. See                                                                                                                                 | e 37 CFR 1.85(a).                                                            |  |  |  |  |
| Replacement drawing sheet(s) including the correct                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ion is required if the drawing(s) is obj                                                                                                                            | jected to. See 37 CFR 1.121(d).                                              |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the Ex                                                                                                                                                                                                                                                                                                                                                                                                                                                     | aminer. Note the attached Office                                                                                                                                    | Action or form PTO-152.                                                      |  |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign                                                                                                                                                                                                                                                                                                                                                                                                                                                         | priority under 35 U.S.C. § 119(a)                                                                                                                                   | )-(d) or (f).                                                                |  |  |  |  |
| a) All b) Some * c) None of:                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                     |                                                                              |  |  |  |  |
| 1. ☐ Certified copies of the priority documents have been received.                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                     |                                                                              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <ul><li>2. Certified copies of the priority documents have been received in Application No</li></ul>                                                                |                                                                              |  |  |  |  |
| 3. Copies of the certified copies of the prior                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                     |                                                                              |  |  |  |  |
| application from the International Bureau                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | · ·                                                                                                                                                                 | ed in this National Stage                                                    |  |  |  |  |
| * See the attached detailed Office action for a list                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                     | ad                                                                           |  |  |  |  |
| dee the attached detailed Office action for a list                                                                                                                                                                                                                                                                                                                                                                                                                                                        | or the octained copies not receive                                                                                                                                  |                                                                              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                     |                                                                              |  |  |  |  |
| Attachment(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | _                                                                                                                                                                   |                                                                              |  |  |  |  |
| 1) Notice of References Cited (PTO-892)                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 4) Interview Summary                                                                                                                                                |                                                                              |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> </ul>                                                                                                                                                                                                                                                                                                                                                   | Paper No(s)/Mail Da 5) Notice of Informal P                                                                                                                         | eatent Application (PTO-152)                                                 |  |  |  |  |
| Paper No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 6) Other:                                                                                                                                                           | · · · · · · · · · · · · · · · · · · ·                                        |  |  |  |  |

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## **DETAILED ACTION**

1. A preliminary amendment was filed on July 21, 2005. Claims 1-150 have been canceled. Claims 151-218 are pending.

## 2. Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 157, 159 and claims 151-156, 160-170, 174-210 reading on omeprazole, drawn to composition containing omeprazole, classified in class 514, subclass 339.
- II. Claim 158 and claims 151-156, 160-170, 174-210 reading on lansoperazole,drawn to composition containing lansoprazole, classified in class 514, subclass 340.
- III. Claims 151-156, 160-170, 174-210, drawn to composition of the remaining subject matter, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of composition with the proton pump inhibitor and buffering agent explicitly named is also required.
- IV. Claims 171-172, drawn to multiple active ingredient compositions, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of composition with the proton pump inhibitor, buffering agent and the further active ingredient i.e. antibacterial agent, etc. explicitly named is also required.

- V. Claims 212-214 and 173, 215-218 in part reading on omerpazole, drawn to liquid dosage formulation, classified in class 514, subclass 339.
- VI. Claims 173, 215-218, drawn to liquid dosage formulation, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of liquid formula with the proton pump inhibitor and buffering agent and liquid carrier explicitly named is also required.

The inventions are distinct, each from the other because of the following reasons:

Each group of invention contain patentably independent and distinct material including proton pump inhibitor, buffering agent and other active ingredient. Unpatentability of any one group of invention does not necessarily mean unpatentability of the other groups of invention. A search for each group for its specific elements of the composition would not be required for another group which does not have the identical elements of the composition, thus, is not coextensive. The merit of each invention depends on the specific element, carrier and dosage of each composition, thus, must be searched, and examined independently.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. In the instant case, then

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there could have been no patentability of all the claims over US 5,447,918, see col. 14, lines 55-68 example 7 containing omerprazole and calcium carbonate which anticipated group I invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang Jan. 5, 2006 Celia Chang
Primary Examiner
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